

## **LOCKABLE CONTAINER WITH INTEGRAL INTERNAL TRAY**

### **CROSS-REFERENCE TO RELATED APPLICATION**

This application claims priority to co-pending U.S. Provisional application 60/523,103, filed on November 19, 2003. The entire disclosure of that prior filed application is hereby incorporated by reference.

### **FIELD OF THE INVENTION**

This invention relates to a two-piece package, which houses portable items on an inner slide card with integral tray configured to be inserted into an outer sleeve. This package may have one or more internal or external locks that prevent the slide card from being pulled out of the sleeve. This senior-friendly package may include a child-resistant feature and a spill-resistant feature, in a package that can be opened and closed numerous times to access the items on the tray.

### **BACKGROUND OF THE INVENTION**

Conventional pharmaceutical packaging has shortcomings with regard to drug delivery devices, which create problems for both the manufacturer and end user. For example, it is known to distribute devices including syringes, vials, ampoules, test tubes, and similarly shaped elongated components in packaging that incorporates foam or plastic elements to separate and pad the device or device component. The manufacturer that incorporates foam or plastic elements in its packaging to protect the device carries an increased inventory and employs a more complicated manufacturing system to produce its packaging. Further, the conventional manufacturer typically produces one kind of package to be filled by automated means and another kind to be filled by hand, which increases inventory and the number of product lines.

In addition, conventional manufacturers pack drug delivery devices tightly and in the most efficient manner possible -- from the perspective of shipping cost savings -- at the expense of the end user who has limited physical mobility, such as an end user with arthritis of the fingers. Such conventional packaging normally orients the device in the difficult to access vertical

position; and, where conventional packaging orients the device in a horizontal position the devices are typically stacked directly on top of each other. It is also known to distribute such devices loose -- or loose, but individually wrapped -- in conventional boxes without a means for holding and securing the devices.

Conventional manufacturers of drug delivery device packaging typically do not provide a child-resistant feature to prevent unauthorized access, or a stopping feature to prevent accidental spillage of the stored products. Where these features do exist, they exist at the expense of easy access for the end user with limited dexterity. Neither does the known drug delivery device packaging provide ample space to place consumer information in the form of appropriately sized graphics, an integral holder for data storage such as a pamphlet or mini-disc, or instructional indicia adjacent to each device. Also conventional manufacturers are not known to mix devices but only distribute similar devices together. This convention requires the end user with a complicated drug regimen to create and maintain an unnecessarily extensive inventory of drug delivery devices to fill their needs.

End users are familiar with the disposal problems created by the use of drug delivery devices. Typically, spent vials, ampoules, test tubes, and components must be sealed or otherwise protected in order to be disposed of safely. While it is known to dispose of needles in a separate sealable and rigid container, there remains a need for packaging that serves as a safe means of disposal for similar devices, such as spent containers.

It is apparent from a survey of the packaging arts that there exists a need for a system and apparatus that secures and protects items such as drug delivery devices and components thereof, allows for improved manufacturing processes, may include child-resistant and spill-prevention features, stores a variety of items in response to the end users' needs, is fitted for easy access by the end user with limited dexterity, has sufficient area to receive graphics and related information, and provides a means for safe disposal.

## **SUMMARY OF THE INVENTION**

The present invention fulfills the needs identified above by providing packaging that comprises an outer sleeve and an inner slide card with an integral tray releasably retained within the outer sleeve. In some embodiments, both the outer sleeve and inner slide card with tray

comprise a means for engaging configured to cooperatively engage the other to create a means for locking, means for releasing, and means for stopping.

In exemplary embodiments, a means for engaging includes panels, tabs, catches, ribs, abutments, edges, cutouts, apertures, and like elements, integral to or attached to the card, configured to connect with similar means for engaging elements associated with the outer sleeve, and referred to herein together as a means for locking. A means for releasing includes panels, tabs, ribs, abutments, edges, cutouts, catches, apertures, and like elements, integral to or attached to the outer sleeve, configured to uncouple engaged or locked elements. With a means for locking and a means for releasing, the present invention provides an optional child-resistant feature. A means for stopping includes panels, tabs, ribs, catches, abutments, apertures, edges, cutouts, and like elements, integral to or attached to the card, configured to matingly engage similar elements associated with the outer sleeve. With a means for stopping, the present invention provides an optional spill-resistant feature to prevent the user from pulling the tray completely away from the outer sleeve.

Embodiments include a system and method for holding and securing portable items, such as drug delivery devices, by providing a slide card with tray configuration that holds and secures a device, allows easy access to the device for removal and replacement; and collects and stores the spent devices. Accordingly, embodiments of the present invention provide a system and apparatus that is able to safely ship drug delivery devices for transepidermal, oral, or hypodermic administration, including pre-filled syringes, vials, ampoules, test tubes, patches, inhalers, and parts thereof, and like devices, safely store the unused devices, and safely store the used devices until all can be safely disposed as a unit.

Alternative embodiments include an apparatus and method for providing product instructions, such as compliance directions and patient information literature (PIL). In one embodiment, indicia -- such as but not limited to time of day, days of the week, numerical sequence, or dosage amounts -- is positioned adjacent to the devices. In another embodiment, information is positioned on or in the inner slide card or outer sleeve in a manner easily visible by the user. One embodiment for securing information comprises a pocket integral to the outer sleeve, while another embodiment comprises a computer disc receiving mount.

Another embodiment of the present invention comprises a slide card with an integral tray and integral engaging tab, wherein the tray is configured to receive and hold at least one

portable item. An outer sleeve that receives the card with tray comprises a locking edge configured to engage the tab at a locking position. Here the outer sleeve defines a void configured to receive the card and tray, and comprises a means for engaging the card's means for engaging. The outer sleeve also includes a means for releasing, configured to uncouple the means for locking created by the coupling of the respective means for engaging.

A method for resisting access to an item secured in an embodiment of the present invention comprises the following steps, presented in the following order merely for the purposes of teaching and not limitation. Provide a slide card with an integral tray and means for engagement. Provide a tray comprising at least one receiving recess, and place an item in the recess. Provide an outer sleeve with an open end, an accessible void, and a means for engaging the card. Align the card with the open end and orient the respective means for engaging to create a means for locking. Insert the card fully into the void to cause the respective means for engaging to releasably lock.

Embodiments according to this invention offer at least the following advantages: lightness in weight, resistance to tampering, child-resistance, ease of access, excellent durability, ease of manufacturing and assembly, device protection, ease of storage, ease of disposal, the ability to present devices of varied and unusual shapes, and excellent economy.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is an isometric view of an embodiment of an inner slide card with integral tray;

FIG. 2 is a plan view of the blank of the inner slide card of FIG 1;

FIG. 3 is an isometric view of an alternative embodiment of an inner slide card with integral tray;

FIG. 4 is a plan view of the blank of the inner slide card of FIG. 3;

FIG. 5 is a plan view of an embodiment of an outer sleeve blank;

FIG. 6 is an isometric view of a constructed embodiment of the present invention.

### **DETAILED DESCRIPTION OF THE INVENTION**

As required, detailed embodiments of the present invention are disclosed herein. It will be understood that the disclosed embodiments are merely exemplary of the invention that may

be constructed in various and alternative forms. The figures are not necessarily to scale, and some features may be exaggerated or minimized to show details of particular components. In other instances, well-known materials or methods have not been described in detail in order to avoid obscuring the present invention. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but as a basis for the claims and for teaching one skilled in the art to variously employ the present invention.

Referring now to the drawings, wherein like numerals represent like features throughout, there are illustrated embodiments of the present invention. Turning first to FIG. 1 and FIG. 2, there is shown a slide card blank **10** configured to form an inner slide card with integral tray **12** configured to receive and store an item, such as a drug delivery device.

Herein, the phrase "drug delivery device(s)" is used broadly to refer to all apparatus and parts thereof used in conjunction with transferring substances into or out of a body, such as but not limited to a human being. By way of example and not limitation, a drug delivery device comprises a substance in the form of, or contained within, pills, tablets, suppositories, chewables, aerosols, inhalers, transdermal patches, injectable devices, parts thereof, and the like. Injectable devices comprise components such as syringes, vials, ampoules, and the like, that may be used by a medical professional to treat a patient with a pharmaceutical drug, or the patient to treat him or herself. For purposes of teaching and not limitation, the illustrated embodiments are configured to receive and store a drug delivery device in the form of injectable devices, but those skilled in the art will immediately understand that the tray may be configured to hold any portable item.

As best shown in FIG. 2, the illustrated blank **10** comprises a base panel **14**, spine panel **16**, inside top panel **18** and outside top panel **20**. The top panel **20** comprises integral spine support panels **22** formed by cut lines **23** and fold lines **24**. Blank **10** further includes extension panel **26**. Depending upon the material used to construct the card, fold lines are formed by scores, cuts, bends, perforations, live hinges, formed hinges, and the like. The extension panel **26** comprises a first securing section **28**, a first sidewall section **30**, a top section **32**, a second sidewall section **34**, and a second securing section **36**. Further, sidewall sections **30**, **34** comprise at least one receiving aperture **38** while top section **32** comprises at least one securing tab **40**. Alternative receiving aperture configurations are described below to illustrate a means for securing to a tray.

Blank **10** further includes engaging tab **42** with engaging edge **44**. As described in detail below, engaging tab **42** cooperatively engages with another element to create a child-resistant feature, and with yet another element to create a pull-out stop that also functions as a spill-resistant feature. Thus tab **42** may function as a means for engaging that is part of a means for locking and/or as part of a means for stopping, by cooperatively engaging with a first element to create the child-resistant feature or cooperatively engaging with a second element to create the spill-resistant feature.

With regard to choice of materials, the blank **10** may comprise paper, paperboard, cardboard, plastic, or combinations thereof. Where the blank **10** comprises paperboard, bleached sulphate, solid unbleached sulphate, or clay-coated newsback are well-known design choices. Typically the paperboard coating is a fluid blend of materials, such as coating clay, calcium carbonate, and/or titanium dioxide with starch or adhesive smoothly applied to the traveling surface. Successive densification and polishing finish the mineral-coated surface to a superior, graphic-print surface. When the card and/or tray is plastic, fabrication techniques well known to those skilled in the art, including thermo-forming, injection molding, and the like, are contemplated. Where the slide card **10** is plastic, the fold-lines **24**, **24b** may be live hinges, or, as explained below regarding the engaging feature of the tab **42**, fold-line **24b** may be a formed hinge with an upwardly or downwardly extending profile to create an internal spring tension that urges the tab **42** back toward a relatively relaxed or horizontal orientation after the tab **42** is first folded over toward base panel **14**.

With regard to assembly, blank **10** may be folded and connected, using conventional techniques, to create the slide card with integral tray **12**, best shown in FIG. 1. One sequence of folding and connecting is as follows, with reference to the visible side of the illustrated blank **10** as the face and the opposite side as the back. The face of top panel **20** is folded and affixed to the face of top panel **18** so that the face of spine support panel **22** (or panels **22**, where a particular embodiment has more than one spine support), overlaps the face of spine panel **16**. The extension panel **26** is folded to form the integral tray. The steps of creating the integral tray may comprise affixing the face of the first securing section **28** to the face of the base panel **14**, folding the first sidewall section **30**, top section **32**, and second sidewall section **34** toward each other to form a sleeve or open-end channel. With the faces of sections **30** and **34** oriented toward each other, the face of second securing section **36** may likewise be attached to the face

of base panel 14. In addition, as described below, engaging tab 42 may be folded so that the face of engaging tab 42 is oriented toward the face of base panel 14.

After assembly, the illustrated tray 12 is configured to receive and store an injectable device such as a vial or ampoule (not shown), shaped, for the purpose of teaching and not limitation, such that a neck is narrower than the body or top. The tray comprises a means for holding the device, such as the rounded receiving aperture 38. The device may be held within the tray by positioning the neck within the receiving aperture 38 and allowing the body to rest on the backs of the securing panels 28, 36. Here, the aperture 38 is rounded because this shape holds a container neck in a particular position while allowing easy access. Those skilled in the art will understand that the aperture 38, as a means for holding, may be configured in various shapes, depending on the device and ease or complexity of access desired. For example, this means for holding may be in the shape of an hour-glass, or "J," or "L," or "G," or "H," all of which provide varying levels of security and access for the items.

The top panel 32 comprises at least one securing tab 40, proximate to the aperture 38, configured to cooperatively engage and secure the device within the tray 12. This securing tab 40, functioning as a means for resisting removal, may be configured to lock in or otherwise secure the item in the aperture. By way of example and not limitation, this means for resisting removal may be a securing tab proximate to the aperture, a fold-over locking flap above or behind the aperture, a strap over the aperture, an insert of different materials such as plastic or rubber yokes within the aperture, and the like, all of which serve to resist removal of the device.

Those skilled in the art will understand that the aperture 38, as a means for holding, and the securing tab 40, as a means for resisting removal, may be configured in various shapes depending on the device and ease or complexity of access desired, without departing from the scope of the claims. To that end, depending upon the shape and size of the devices to be held on the tray, various configurations of a means for holding and a means for resisting removal -- whether those configurations are shaped to hold similar or different devices -- may be formed in extension panel 26 so that the related tray is configured to hold and secure the intended devices.

FIG. 4 shows an alternative embodiment of a card blank 100 that, when assembled, forms the inner card with integral tray 102 shown in FIG. 3. The illustrated blank 100 comprises a base panel 104, spine panel 106, inside top panel 108 and outside top panel 110. The top

panel **110** comprises a spine support panel **112** formed by cut lines **113** and fold lines **114**. Blank **100** further comprises first extension panel **116** and second extension panel **118**.

The extension panel **116** comprises first sidewall section **120**, a top section **122**, a second sidewall section **124**, and a securing section **126**. Further, sidewall section **124** comprises at least one receiving aperture **128** while top section **122** comprises at least one securing tab **130**. For the purposes of teaching and not limitation, the extension panels **116**, **118** are illustrated with different configurations. Here, panel **116** comprises both a means for holding and a means for resisting removal, while panel **118** has neither. Those skilled in the art will understand that, in this embodiment, panel **118** serves to add rigidity to the package and protect the devices held and secured by panel **116**. Further, they will understand that panel **118** may likewise be configured to comprise a means for holding and a means for resisting removal.

Blank **100** further comprises engaging tab **132** with engaging edge **133**. Similar to engaging tab **42** with edge **44** described herein, engaging tab **132** cooperatively engages with another element to create a child-resistant feature, and with yet another element to create a pull-out stop that also functions as a spill-resistant feature. Thus tab **132** may function as a means for engaging that is part of a means for locking and/or as part of a means for stopping, by cooperatively engaging with a first element to create the child-resistant feature or cooperatively engaging with a second element to create the spill-resistant feature.

With regard to assembly, blank **100** may be folded and connected, using conventional techniques, to create the slide card with integral tray **102** best shown in FIG. 3. One sequence of folding and connecting is as follows, with reference to the visible side of the illustrated blank **100** as the face and the opposite side as the back. The face of top panel **110** is folded and affixed to the face of top panel **108** so that the face of spine support panel **112** overlaps the face of spine panel **106**. The extension panels **116**, **118** are folded to form the integral tray. The steps of creating the integral tray may comprise folding the first sidewall section **120**, top section **122**, and second sidewall section **124** toward each other to form a sleeve or open-end channel. With the faces of sections **120** and **124** oriented toward each other, the face of securing section **126** may be attached to the face of base panel **104**. In addition, as described below, engaging tab **132** may be folded so that the face of engaging tab **132** is oriented toward the face of base panel **104**.



Here the trays **12**, **102** are configured to allow for easy access to the items being held and stored. By way of illustration and not limitation, the devices may be arranged so that the end user, who may have limited physical mobility such as arthritis, can retrieve one device without affecting another. For example, orienting an item horizontally and with its widest part splayed across the panel **14**, **104** or sections, **28**, **36**, **126**, provides the greatest accessibility to the item, which is a desirable feature of certain embodiments. Such horizontal orienting also provides easy viewing of the devices so the user may easily distinguish between them. Further, such orienting provides ample area to receive graphics. For example, dosage regimen instructions including date, day, and time may be formed on the tray sections between or adjacent to the recesses. Alternatively, the items held on the tray may be as closely packed and aligned as desired.

User information such as dose compliance, warnings, instructions, patient information literature (PIL), and similar data in written or digital form can be made easily visible or accessible to the user through the ample billboard space found on either side of the many panels described herein. In one embodiment, best shown in FIG. 3 and FIG. 4, there is shown a means for data storage, which receives and stores data mediums. Here data storage **134** is formed by semi-circular storage cut line **136** and storage score line **138**, in outside top panel **110**. When outside top panel **110** is folded over and affixed to inside top panel **108**, cut line **136** and score line **138** provide a receiving slot and storage sleeve for receiving and storing information such as may be provided in a brochure or an electronic disc. Another means for data storage includes an electronic disc mount for securing the disc hub of a CD or mini-DVD, and may be positioned on any of the panels described herein.

Turning now to FIGS. 5 and 6, there is shown an outer sleeve **200** for receiving the inner card with integral tray **12**, **102**, and the related outer sleeve blank **202**. As best shown in FIG. 5, the illustrated blank **202** includes side panels **204**, **206**, **208**, spine panels **210**, end panels **212**, **214**, and extension panels **216**. The panels are defined by the respective adjacent fold lines **24** and respective outer edge **218**. Extension panel **216** includes outer edge **220**. In addition, side panel **208** includes an indent **222**, which, as explained below, is configured to surround or otherwise avoid the release button **224** located on side panel **204**. The release button **224** is defined by cut line **23** and fold line **24**. Side panel **204** also comprises an internal engaging edge **240**, created by the cut line **23** that defines the release button **224**, that defines a means for engaging.

With regard to assembly, the blank **202** is folded and connected using conventional techniques to create the outer sleeve **200**, best shown in FIG. 6 as a slip case defining a void **226**. One sequence of folding and connecting the blank **202** is as follows, with reference to the visible side of the illustrated blank **202** as the face and the opposite side as the back. Side panel **208** is folded, along fold lines **24**, under the side panels **206**, **204** and then positioned over panel **204** so that the back of panel **208** may be affixed to the face of panel **204**. In this embodiment panel **208** is overlayed and affixed to panel **204** so that the indent **222** of panel **208** surrounds or otherwise avoids the release button **224**. In other words, the release button **224** is unobstructed by panel **208**.

Extension panels **216** are folded inwardly to extend into the void **226** so that edges **220** float freely to define a means for engaging, and end panels **212**, **214** are folded inwardly so that the face of one end panel may be affixed to the back of the other to form the end wall of the slip case. In some embodiments the back of panels **216** are affixed to the backs of the respective adjacent side panels **204**, **206**. In those embodiments the edges **220** are immediately adjacent to the backs of panels **204**, **206** and act, as described below, as a means for engaging. The cutouts **230** form finger-access areas when panels **216** are folded.

In practice, and with reference to FIGS. 1 and 6, items are placed within the tray and the various panels and tabs are folded before the inner card with integral tray **12**, **102** is inserted into the void **226** of outer sleeve **200**. This container holds and protects the items until they are retrieved for use. In the example of drug delivery devices holding a unit dose, the illustrated Unit Dose Packaging System (UDPS) secures these devices until they are retrieved for use. For purposes of teaching and not limitation, the following folding sequence is described. Top panel **20** is folded so as to cover the tray and the spine support panel **22** is oriented to be adjacent to spine **16**, so as to provide support for the spine **16**. In the illustrated embodiment, the back of top panel **20** is now adjacent to the items and substantially parallel to panel **14**. Further, engaging tab **42** is folded inwardly so that the face of tab **42** is close to or touching the face of base panel **14**. With the inner card folded as described, it is inserted into the void **226**, through the open end, starting with the edge formed by the fold line **24b**, and with tab **42** receivingly aligned with release button **224**, as illustrated in FIG. 6.

The card with tray **12**, **102** may be fully inserted into the outer sleeve **202**, to a fully closed position. With continued reference to FIG. 6 and as understood by those skilled in the art, the spring tension created by the inwardly folded tab **42** causes the engaging edge **44** to

press against the interior of the void **226** along panel **204**. Two particular points of contact along the interior of the void will be noted. At the fully closed position the engagement of tab edge **44** with the internal edge **240** creates the means for locking at position **A** that provides the child-resistant feature. From a fully opened position, the engagement of the tab edge **44** with the interior of the folded extension panel **216** creates the means for stopping at position **B** that provides the spill-resistant feature. It will be understood that an embodiment may be constructed without either or both of the child-resistant or spill-resistant features.

In the illustrated embodiment a means for releasing includes the release button **224**. The spring tension created by the folded tab **42** causes the leading edge of tab **44** to engage the internal edge **240** of the panel **204**. With the edge **44** and edge **240** engaged, the inner card with integral tray is locked within the outer sleeve **200** and cannot be accessed; this means for locking creates a child-resistant feature. To unlock the child-resistant feature of this embodiment and thereby release the card with tray, the user depresses the release button **224**, which in turn depresses the tab **42** to disengage the edge **44** from the edge **240**.

After releasing the optional child-resistant feature the card with tray **12** may be extracted from the outer sleeve **200** to a fully open position. In the illustrated embodiments, a fully open position occurs when tab **42** engages the interior of floating extension panel **216** at stopping position **B**. As will be understood by those skilled in the art, the spring tension created by the folded tab **42** causes the tab **42** to engage the interior of the floating extension panel **216**. Once engaged, the card with tray **12** cannot be further removed from the outer sleeve **200** but may be reinserted to a fully closed position if desired. In this manner, this means for stopping acts as a spill-resistance feature to prevent the card with tray **12** from being pulled completely out of outer sleeve **200**.

It will be understood that a means for releasing, a means locking, and a means for stopping, are contemplated in various combinations in various embodiments. For example, in the illustrated embodiment the extension panel **216** is not attached to side panel **204**, but is allowed to extend downwardly into the void **226** to catch and engage the folded tab **42**, thereby forming a means for stopping. In an alternative embodiment the extension panel **216** is folded inwardly and the respective backs of the panels **216**, **204** are attached so that the extension panel edge **220** abuts engaging edge **44**, thereby forming a means for stopping. In the illustrated embodiment the release button **224** and edge **44** have similar profiles, a feature that facilitates engagement of the respective edges **240**, **44** and forms a means for locking. In

alternative embodiments any edge or protrusion within the void 226 configured from panels, tabs, cutouts, ribs, offsets, catches, apertures, abutments, edges, and like elements, that engage similar elements such as the tab 42 or tab edge 44, forms an alternative means for locking or an alternative means for stopping. In yet another embodiment, a means for engaging is integral to or connected to the extension panels 26, 116, 118 to create a means for locking and a means for stopping.

The user may open and close the container by withdrawing and replacing the card with tray 12, 102 within the outer sleeve 200 as often as desired. Regarding the illustrated embodiments, from the locked position A the user grasps the card with tray 12 at the top panel 18 and base panel 14, both adjacent to the spine panel 16, from the access cutouts 230 provided in side panels 204, 206, 208. The user then depresses the release button 224 in order to disengage the means for locking. Continuing to depress the button 224 while grasping and pulling laterally will withdraw the tray from the sleeve 200. From the stopped position B the user may fold back the optional top panel 20 to access an item held in the tray. After accessing the desired item, the user folds the top panel 20 back over the tray and reinserts the card with tray 12 within the sleeve 200 for future use.

An embodiment designed to be disposed of, together with used injectables, may be placed within a red plastic bag (not shown but provided with the embodiment) thereby giving notice of the contents. By way of illustration and not limitation, additional means for protecting and sealing an embodiment to be disposed of, together with used injectables, include sealable bags, a self-sealing outer sleeve, a sealable outer sleeve large enough to receive the inner card with tray and outer sleeve 200. Similarly, taping the card within the outer sleeve with red tape giving notice of the contents is another means for protecting and sealing.

It is contemplated that the present invention is not limited to the pharmaceutical-related goods illustrated, but is applicable to a plethora of delicate, sensitive, or unique portable goods. By way of example and not limitation, small electronic components, jewelry, foods, expensive and precious articles, and any other item that requires a safe, stable, and portable environment in which to be shipped and stored may find an application with the present invention. Further, it will be understood that variations, modifications, and enhancements can be made to the disclosed apparatus and methods without departing from the scope of the present invention as defined in the following claims.